Special 510(k): Device Modification
Gianturco-Roehm Bird's Nest® Vena Cava Filter
COOK INCORPORATED
26 February 2008

510(k) SUMMARY

Submitted By: Molly Busenbark
Cook Incorporated
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Bloomington, IN
Phone: (812) 339-2235 x 2162
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Device:

Trade Name:	Vena Cava Filter
Proposed Classification:	21 CFR 870.3375 Class II Cardiovascular Intravascular Filter

Indications for Use:

The Gianturco-Roehm Bird's Nest® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

1. Pulmonary thromboembolism when anticoagulants are contraindicated;
2. Failure of anticoagulant therapy in thromboembolic diseases;
3. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
4. Prophylactically in patients with chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Predicate Device:

The Gianturco-Roehm Bird's Nest® Vena Cava Filter is similar in terms of intended use, materials of construction, and technological characteristics to the predicate Gianturco-Roehm Bird's Nest® Vena Cava Filter.

Device Description:

The Bird's Nest® Vena Cava Filter is a permanent cardiovascular intravascular filter intended for percutaneous insertion into the inferior vena cava positioned below the renal veins and above the iliac veins. The Bird's Nest® Vena Cava Filter utilizes a fine-wire stainless steel multiplane filtering system. The Bird's Nest® Vena Cava Filter is placed via standard percutaneous entry (Seldinger) technique with fluoroscopic control.

Access sites include both left and right femoral, and left and right internal jugular veins. The 11.0 French delivery catheters are available in a 45 cm length for femoral vein approach and a 75 cm length for jugular vein approach.

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The Bird's Nest® Vena Cava Filter is designed for use in vena cava measuring up to 40 mm in diameter. Caval measurements should be performed prior to filter insertion, and care should be taken to ensure proper strut fixation.

The basic function of the filter relies upon shape memory properties of the stainless steel wire which is used for its construction. Four strands of 0.18 mm stainless steel surgical wire, each 25 cm long before forming, are shaped to have 15-20 fine wave bends formed into each wire. Please refer to Figure 1 for a representative picture of the deployed Bird's Nest® Vena Cava Filter.

Two pairs of hooks, one pair proximal and one pair distal, hold the filter in position. The pairs of hooks are attached to each end of the four wire strands by junction points. The hooks spring out of the catheter and engage the vessel wall. The hooks and the lateral pressure exerted by the preformed curved wires fix the device securely into the vessel wall.

Substantial Equivalence:

The existing filter has not been modified. In this submission, Cook Incorporated is extending the length of the introducer system and modifying the tip of the introducer.

Cook Incorporated currently markets the predicate Gianturco-Roehm Bird's Nest® Vena Cava Filter, which is substantially equivalent to the Gianturco-Roehm Bird's Nest® Vena Cava Filter, subject of this submission. The similar indications for use and technological characteristics of the Gianturco-Roehm Bird's Nest® Vena Cava Filter as compared to the predicate device support a determination of substantial equivalence.

Test Data:

The proposed Gianturco-Roehm Bird's Nest® Vena Cava Filter was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Packaging Design Validation Report
- Bioburden, Residual, and Endotoxin Testing
- Deployment Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2008

Cook Incorporated
c/o Ms. Molly Busenbark
Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402

Re: K073528
Gianturco-Roehm Bird's Nest Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: January 25, 2008
Received: January 28, 2008

Dear Ms. Busenbark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k): Device Modification
Gianturco-Roehm Bird's Nest® Vena Cava Filter
COOK INCORPORATED
14 December 2007

Indications for Use

510(k) Number (if known): K073528

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B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073528

Prescription Use XX (Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)